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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,513	12/21/2004	Jeremy Marshall	3003-1159	8360
466	7590	01/10/2008		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER SONNETT, KATHLEEN C	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/518,513	Applicant(s) MARSHALL, JEREMY	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 12-14 and 17 have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment to claim 12. Regarding the rejection of claims 15 and 16, it is noted that claim 15 does not include the new limitations of amended claim 12 as it is an independent claim. Since the arguments presented by applicant deal with how the newly added limitations of claims 12-14 and 17 differentiate the claimed invention from the prior art of Crossman, the 35 USC 103(a) rejections of claims 15 and 16 have been maintained over Crossman in view of Higgins.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 12-14 and 17** are rejected under 35 U.S.C. 102(b) as being anticipated by Beiter (US 4,545,376). Beiter discloses a lancet comprising a needle having a pointed tip, a support body enclosing the needle such that the pointed tip projects beyond the end of the support body, a removable guard located over the pointed tip of the needle, the guard being integrally molded from plastics material with the support body and connected thereto by a breakable neck portion, the removable guard portion having an outer peripheral thickened region describing a generally U-shape or C-shape, a central region of thinner section and a further thickened region being spaced from the adjacent ends of the peripheral thickened region such that there is a gap therebetween bridged only by the thinner section (see abstract and fig. 1). In particular, looking

at the thickened section that includes the hole (32), the material can be considered a u-shape around the hole. As seen in fig. 4, there is a small amount of this thickened section distal of the hole (32) before the next groove (34). This section is attached to another thickened region (in either proximal or distal direction) only by a thinner section (one of the grooves 34).

4. Regarding claim 13, the device includes a centrally positioned hole (32) close to the end of the guard remote from the needle point.

5. Regarding claims 14 and 17, the guard is generally tab-like in form and the thickened region surrounding the hole can be considered arc-like portions on two side edges of the guard which lead to the thinner section of the plastics material (groove 34) adjacent the needle tip.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 15 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman in view of Higgins. Crossman discloses a lancet having a support body enclosing a needle (6) such that a pointed tip of the needle projects beyond the end of the support body (1) and a removable guard (4) located over the pointed tip of the needle and interconnected with a support body holding the needle via a breakable neck portion (5) molded with the guard and support body, the guard being formed of a molded plastics material (see abstract). The guard includes an outer edge thickened region leading from the end of the guard remote from the needle tip to a thinner section of the plastic material approaching the needle tip, the plastics

material forming a further thickened region about the needle tip but separated from the outer edge region by the thinner section. Crossman discloses integrally molding the guard and support body (see abstract) but does not disclose the particulars of the mold used to form the device such as the shape or an entry point for the plastic.

8. However, Higgins discloses that it is old and well known in the art to form a lancet using features of the mold to form the shape of the lancet. The needle is held in the mold as seen in fig. 12 and plastics material is injected into the mold via an entry point (88) to crease the guard about the needle tip (col. 4, ll. 46-52). In order to make the lancet of Crossman, it would have been obvious to form the mold with an outer edge thickened hollow region that leads to a thinner hollow section approaching the needle tip and a further enlarged hollow region about the needle tip since such shape a shape would result in the lancet of Crossman as Higgins discloses that injecting plastic into an entry point forms a lancet shaped by the mold.

9. Regarding claim 16, Crossman discloses that holes (3) are formed by pins that hold the needle during the molding process. Crossman is silent on how hole (8) is formed. However, since Crossman discloses that pins connected to the mold can form holes in the lancet, it would have been obvious to one skilled in the art to form the other hole using a pin. Since the entry point for the plastics is at the distal end of the mold (see fig. 13 of Higgins), and the pin must be located centrally such that it forms hole (8), the material will flow around both sides of the pin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 12/28/2007


GLENN K. DAWSON
PRIMARY EXAMINER